

§ 864.3250 Specimen transport and storage container.

(a) *Identification.* A specimen transport and storage container, which may be empty or prefilled, is a device intended to contain biological specimens, body waste, or body exudate during storage and transport in order that the matter contained therein can be destroyed or used effectively for diagnostic examination. If prefilled, the device contains a fixative solution or other general purpose reagent to preserve the condition of a biological specimen added to the container. This section does not apply to specimen transport and storage containers that are intended for use as part of an over-the-counter test sample collection system for drugs of abuse testing.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180 of this chapter, with respect to general requirements concerning records, and § 820.198 of this chapter, with respect to complaint files.

[54 FR 47206, Nov. 13, 1989, as amended at 65 FR 2310, Jan. 14, 2000; 65 FR 18234, Apr. 7, 2000]

§ 864.3260 OTC test sample collection systems for drugs of abuse testing.

(a) *Identification.* An over-the-counter (OTC) test sample collection system for drugs of abuse testing is a device intended to: Collect biological specimens (such as hair, urine, sweat, or saliva), outside of a medical setting and not on order of a health care professional (e.g., in the home, insurance, sports, or workplace setting); maintain the integrity of such specimens during storage and transport in order that the matter contained therein can be tested in a laboratory for the presence of drugs of abuse or their metabolites; and provide access to test results and counseling. This section does not apply to collection, transport, or laboratory testing of biological specimens for the presence of drugs of abuse or their me-

tabolites that is performed to develop evidence for law enforcement purposes.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification requirements in part 807, subpart E of this chapter subject to the limitations in § 864.9 if it is sold, distributed, and used in accordance with the restrictions set forth in § 809.40 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.198 of this chapter with respect to complaint files.

[65 FR 18234, Apr. 7, 2000]

§ 864.3300 Cytocentrifuge.

(a) *Identification.* A cytocentrifuge is a centrifuge used to concentrate cells from biological cell suspensions (e.g., cerebrospinal fluid) and to deposit these cells on a glass microscope slide for cytological examination.

(b) *Classification.* Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

[45 FR 60588, Sept. 12, 1980, as amended at 54 FR 25044, June 12, 1989; 66 FR 38789, July 25, 2001]

§ 864.3400 Device for sealing microsections.

(a) *Identification.* A device for sealing microsections is an automated instrument used to seal stained cells and microsections for histological and cytological examination.

(b) *Classification.* Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

[45 FR 60589, Sept. 12, 1980, as amended at 54 FR 25044, June 12, 1989; 66 FR 38789, July 25, 2001]

§ 864.3600 Microscopes and accessories.

(a) *Identification.* Microscopes and accessories are optical instruments used to enlarge images of specimens, preparations, and cultures for medical purposes. Variations of microscopes and accessories (through a change in the